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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/822,235 | 04/09/2004 | Susan Gould-Fogerite | BSZ-049 | 1705 |

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LAHIVE & COCKFIELD
28 STATE STREET
BOSTON, MA 02109

| EXAMINER | |
|---|---|
| WHITEMAN, BRIAN A | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1635 | |

DATE MAILED: 04/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/822,235 | GOULD-FOGERITE ET AL. | |
| | Examiner | Art Unit | |
| | Brian Whiteman | 1635 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 1-63 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-63 are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Notice to Comply W/ Seq.*.

## DETAILED ACTION

Claims 1-63 are pending.

This application contains sequence disclosures that are encompassed by the definition for nucleotide sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements for Patent Applications Containing Nucleotide Sequence Disclosures.

Page 77 list sequences that are missing a corresponding SEQ ID NO:.

A complete response to the instant election/restriction should include a response to the Notice to Comply Letter.

Claims 19-22 are method claims, but the claims depend on a product claim. To expedite prosecution of the case and absence evidence to the contrary, the examiner will assume that claims 19-22 depend on claim 14 and not claim 11.

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4, 6, and 8-13, drawn to an siRNA-cochleate composition comprising a cochleate and an siRNA associated with the cochleate, wherein the siRNA mediates interference against a target mRNA expressing a cancer protein, classifiable in class 514, subclass 44.

II. Claims 1-4, 6, and 8-13, drawn to an siRNA-cochleate composition comprising a cochleate and an siRNA associated with the cochleate, wherein the siRNA

mediates interference against a target mRNA expressing a viral protein (HIV protein), classifiable in class 514, subclass 44.

III. Claims 1-4, 6, and 8-13, drawn to an siRNA-cochleate composition comprising a cochleate and an siRNA associated with the cochleate, wherein the siRNA mediates interference against a target mRNA expressing a fungal protein, classifiable in class 514, subclass 44.

IV. Claims 1-4, 6, and 8-13, drawn to an siRNA-cochleate composition comprising a cochleate and an siRNA associated with the cochleate, wherein the siRNA mediates interference against a target mRNA expressing a bacterial protein, classifiable in class 514, subclass 44.

V. Claims 1-4, 6, and 8-13, drawn to an siRNA-cochleate composition comprising a cochleate and an siRNA associated with the cochleate, wherein the siRNA mediates interference against a target mRNA expressing an abnormal cellular protein, classifiable in class 514, subclass 44.

VI. Claims 1-4, 6, and 8-13, drawn to an siRNA-cochleate composition comprising a cochleate and an siRNA associated with the cochleate, wherein the siRNA mediates interference against a target mRNA expressing a cellular protein, classifiable in class 514, subclass 44.

VII. Claims 7 and 43, drawn to an siRNA-cochleate composition comprising a cochleate and an siRNA associated with the cochleate and further comprising a second siRNA directed against a second target mRNA, classifiable in class 514, subclass 44.

VIII. Claims 14-24, 44-51 and 62-63, drawn to a method of treating a subject having a disease or a disorder associated with expression of a target mRNA comprising administering to a subject an siRNA-cochleate composition, classifiable in class 424, subclass 93.2.

NOTE: Claims 24 and 63 list numerous diseases and disorders that would require the examiner to place each disease or disorder into a separate, which would result in over 100 groups. If applicants elect group VIII, applicants are further required to elect a specific disease or disorder from claim 24 and 63. Each disease or disorder is unrelated because each disease requires a different subject and different target mRNA. It would be an undue burden on the examiner to search every disease or disorder listed in the claims because each disease or disorder requires a distinct subject. This is not a species election.

IX. Claims 25-33 and 52-61, drawn to a method of forming a siRNA-cochleate composition comprising precipating a liposome and a siRNA, classifiable in class 424, subclass 450.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions the inventions are unrelated because each invention has a different mode of operation and effect. The inventions are not coextensive because each invention requires targeting an mRNA from a structurally different protein.

Inventions VII and I-VI are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the target mRNA expresses a protein can be selected from a viral protein, a bacterial protein, fungal protein, cancer protein, cellular protein as recited in Inventions I-VI. The subcombination has separate utility such as delivering the composition to a cell in vitro. Furthermore, it would be an undue burden on the examiner to search all of the inventions together because the examiner would have to further search a composition with two siRNAs and a composition comprising one siRNA.

Inventions I-VI and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the composition of groups I-VI can be used to make a composition with several siRNAs as opposed to its use in being delivered to a host.

Searching the inventions of Groups I-VI and VIII together would impose serious search burden. The inventions of Groups I-VI and VIII have a separate search status in the art as shown by their different classifications. Moreover, in the instant case, the search for the compositon and the method of using the composition are not coextensive. Prior art which teaches the composition would not necessarily be applicable to the method of using the composition.

Moreover, even of the composition were known, the method of using the composition may be novel and unobvious in view of the preamble or active steps.

Inventions VII and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are unrelated because the method of Group VIII does not require the composition of group VII.

Searching the inventions of Groups VII and VIII together would impose serious search burden. The inventions of Groups VII and VIII have a separate search status in the art as shown by their different classifications. Moreover, in the instant case, the search for the composition and the method of using a different composition are not coextensive. Prior art, which teaches the composition, would not necessarily be applicable to the method of using the composition. Moreover, even of the composition were known, the method of using the composition may be novel and unobvious in view of the preamble or active steps.

Inventions IX and I-VI are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the process can be used to make the composition set forth in groups I-VI. The product in Groups I-VI can be made by another and materially different process.

Searching the inventions of Groups I-VI and IX together would impose serious search burden. The inventions of Groups I-VI and IX have a separate search status in the art as shown

by their different classifications. Moreover, in the instant case, the search for the composition and the method of producing the composition are not coextensive.

Inventions VII and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are unrelated because the process of Group IX does not require the composition of group VII.

Searching the inventions of Groups VII and IX together would impose serious search burden. The inventions of Groups VII and IX have a separate search status in the art as shown by their different classifications. Moreover, in the instant case, the search for the composition and the method of producing another composition are not coextensive.

Claims 5 and 34-42 link(s) inventions I-VI. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims.

Claims 1 and 34 link(s) inventions I-VII. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 1 and 34. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim(s) including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Because these inventions are distinct for the reasons given above and the search required for each Group listed above is not required for any other Group listed above and the search for each group is not co-extensive, restriction for examination purposes as indicated is proper.

It would be unduly burdensome for the examiner to search and consider patentability of all of the presently pending claims, a restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined

claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 § 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (571) 272-0764.

The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, acting SPE - Art Unit 1635, can be reached at (571) 272-0811.

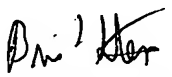
Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center number is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Brian Whiteman, 1635



BRIAN WHITEMAN
PATENT EXAMINER

| Notice to Comply | Application No. 10/822,235 | Applicant(s) GOULD-FOGERITE et al. | |
|---|---|---|---|
| | Examiner B. Whiteman | Art Unit 1635 | |

## NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set in the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

☒ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☒ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☒ 7. Other: Page 77 contains sequences that are missing SEQ ID NOs.

### Applicant Must Provide:

☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

☒ An initial or substitute paper copy of the "Sequence Listing", **as well as an amendment specifically directing its entry into the specification**.

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (571) 272-2510
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